K000056

FEB 24 2000

Biocell® LABORATORIES, INC

510(k) PRODUCT SUMMARY

510(k) Number - K000056

Trade Name - BIO-LIPID HDL/LDL Calibrator

Common Name - HUMAN SERUM LIPID CALIBRATOR

Classification Name: We believe that this product is classified as an *in vitro* diagnostic device, multiple analyte serum calibrator 75 JJX.

Summary - BIO-LIPID HDL/LDL Calibrators are lyophilized products prepared from fresh human sera enriched with human lipid fractions and are designed to calibrate HDL and LDL homogenous cholesterol assays. Each vial contains 1.0mL of stabilized and freeze dried calibrator and is available in two (2) levels, one vial per package. The two levels are designed to calibrate clinical chemistry HDL and LDL cholesterol assays in the significant ranges.

Substantial Equivalence - General Description: The Biocell Laboratories Inc. Bio-Lipid Calibrator is an *in vitro* diagnostic medical device, intended for use with a variety of test kits to provide calibration of quantitative serum lipid determinations for HDL Cholesterol and LDL Cholesterol. These assayed calibrators, when used as described in the enclosed draft labeling, will provide a tool to calibrate HDL and LDL for clinical chemistry assays. The Biocell HDL/LDL Calibrator consists of two levels corresponding to one low and one high serum level.

Similarities and Differences from other commercially available devices: The BIO-LIPID HDL/LDL Calibrators are similar to the following commercially available calibrators: Equal Diagnostics, HDL Direct Liquid Select Cholesterol Calibrator; Equal Diagnostics, LDL Direct Liquid Select Cholesterol Calibrator; Boehringer Mannheim, C.f.a.s. HDL/LDL-C plus; and Randox, Cholesterol Calibrator. For comparative purposes, sample copies of labeling from these currently available lipid calibrators may be found in Attachment E of this submission. The Biocell Laboratories, Inc. BIO-LIPID HDL/LDL Lipid Calibrators are available in two separate levels.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 24 2000

Mr. Marc M. McKonic
Official Correspondent, Regulatory Affairs
Biocell Laboratories, Inc.
2001 University Drive
Rancho Dominguez, California 90220-6411

Re: K000056
Trade Name: Bio-Lipid Human Serum HDL and LDL Calibrator
Regulatory Class: II
Product Code: JIX
Dated: December 28, 1999
Received: January 10, 2000

Dear Mr. McKonic:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): 000056

DEVICE NAME: BIO-LIPID HUMAN SERUM HDL AND LDL CALIBRATOR

INDICATIONS FOR USE:

BIO-LIPID HDL/LDL Calibrators are lyophilized products prepared from fresh human sera enriched with human lipid fractions. Each vial contains 1.0mL of stabilized and freeze dried control and is available in two (2) levels, one vial per package. The two levels are designed to calibrate clinical chemistry HDL and LDL cholesterol assays in the significant ranges.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k000056

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)